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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/411,797	10/01/1999	STEVE A. HERWECK	ATA-257	8813
959	7590	06/10/2004	EXAMINER	
LAHIVE & COCKFIELD, LLP. 28 STATE STREET BOSTON, MA 02109			LAM, ANN Y	
			ART UNIT	PAPER NUMBER

1641

DATE MAILED: 06/10/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

**Advisory Action**

Application No.

09/411,797

Applicant(s)

HERWECK ET AL.

Examiner

Ann Y. Lam

Art Unit

1641

--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE. Therefore, further action by the applicant is required to avoid abandonment of this application. A proper reply to a final rejection under 37 CFR 1.113 may only be either: (1) a timely filed amendment which places the application in condition for allowance; (2) a timely filed Notice of Appeal (with appeal fee); or (3) a timely filed Request for Continued Examination (RCE) in compliance with 37 CFR 1.114.

**PERIOD FOR REPLY** [check either a) or b)]

- a) ☐ The period for reply expires \_\_\_\_\_ months from the mailing date of the final rejection.
- b) ☒ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection. ONLY CHECK THIS BOX WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

1. ☐ A Notice of Appeal was filed on \_\_\_\_\_. Appellant's Brief must be filed within the period set forth in 37 CFR 1.192(a), or any extension thereof (37 CFR 1.191(d)), to avoid dismissal of the appeal.
2. ☒ The proposed amendment(s) will not be entered because:
- (a) ☒ they raise new issues that would require further consideration and/or search (see NOTE below);
- (b) ☐ they raise the issue of new matter (see Note below);
- (c) ☒ they are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or
- (d) ☐ they present additional claims without canceling a corresponding number of finally rejected claims.

NOTE: See Continuation Sheet.

3. ☐ Applicant's reply has overcome the following rejection(s): \_\_\_\_\_.
4. ☐ Newly proposed or amended claim(s) \_\_\_\_\_ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).
5. ☒ The a) ☐ affidavit, b) ☐ exhibit, or c) ☒ request for reconsideration has been considered but does NOT place the application in condition for allowance because: See Continuation Sheet.
6. ☐ The affidavit or exhibit will NOT be considered because it is not directed SOLELY to issues which were newly raised by the Examiner in the final rejection.
7. ☐ For purposes of Appeal, the proposed amendment(s) a) ☒ will not be entered or b) ☐ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.

The status of the claim(s) is (or will be) as follows:

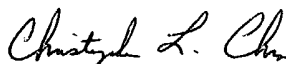
Claim(s) allowed: 45-49 and 53.

Claim(s) objected to: 3.

Claim(s) rejected: 1, 2, 4-27, 44, 50-52.

Claim(s) withdrawn from consideration: \_\_\_\_\_.

8. ☐ The drawing correction filed on \_\_\_\_\_ is a) ☐ approved or b) ☐ disapproved by the Examiner.
9. ☐ Note the attached Information Disclosure Statement(s) (PTO-1449) Paper No(s). \_\_\_\_\_.
10. ☐ Other: \_\_\_\_\_

  
CHRISTOPHER L. CHIN  
PRIMARY EXAMINER  
GROUP 1800/641

Continuation of 2. NOTE: Applicant's amendment changing "first, reduced diameter" to "collapsed" and changing "second, increased diameter" to "expanded" would require further search and consideration. The amendments substantially change the scope of the invention since a member that has a first, reduced diameter configuration deployable to a second, increased diameter configuration, does not necessarily require a collapsed configuration deployable to an expanded configuration, and vice versa. Thus, since the proposed limitations are substantially different from the limitations that Applicant proposes to have replaced, the amendments also do not reduce or simplify the issues for appeal.

Continuation of 5. does NOT place the application in condition for allowance because: With respect to Applicant's remarks regarding original claim 53, Examiner apologizes for the oversight. Original claim 53 was inadvertently indicated by Examiner as being rejected. Claim 53 should have been indicated as being allowable, and Examiner corrects this in the status of the claims in this advisory action.

Applicant also argues on page 11, first paragraph, that Bodick is describing longitudinal stretching of the materials, thereby increasing pore size, and that this does not equate to expanding the diameter (radial) dimension of a tube or balloon formed of ePTFE. Similar arguments are made on page 11, paragraph 3 and 4 and page 12. Examiner agrees that longitudinal stretching does not equate to expanding the diameter of a material. However, Examiner asserts that, given that the sheath is thin and made of ePTFE, and given the structure of the device, i.e., a sheath having pores and with both ends of the sheath being closed, Examiner asserts that the sheath is capable of being expanded radially by fluid pressure. In other words, the sheath is capable of being stretched not only longitudinally, but also radially. Examiner emphasizes that Applicant is claiming a device, as opposed to a method claim, and therefore a recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. In a claim drawn to a process of making, the intended use must result in a manipulative difference as compared to the prior art. See *In re Casey*, 152 USPQ 235 (CCPA 1967) and *In re Otto*, 136 USPQ 458, 459 (CCPA 1963).

Applicant also argues on page 11, second paragraph that ePTFE is inelastic as understood by one of ordinary skill in the art. Examiner disagrees and invites Applicant to view *Huter et al.*, 6,511,496, claim 7, and *Chen*, 6,673,105, column 2, line 45, (neither of which has been cited in any prior Office action, but which Examiner hereby cites to show the inherent characteristics of ePTFE material.) Both of these references show that ePTFE is an elastic material.

Applicant also argues on page 13 that Bodicky teaches that "seal 44 retains a nearly constant diameter for sheath 40 at its proximal end despite any pressure applied to the outer surface of the ePTFE sheath 40 by the patient's urethra" (see Bodicky, column 6, line 67 to column 7, line 2.) Applicant thus argues that an attempt to collapse the sheath in Bodicky is specifically prevented by the seal. Applicant makes a similar argument on page 14, first full paragraph. Examiner does not find this argument persuasive since the seal only prevents collapse of the sheath at the proximal end, i.e., specifically where the seal is located. In other words, the sheath is capable of being collapsed in the other portions of the sheath, i.e., portions where the seal is not present. In any case, applicant is not claiming a collapse configuration in the previous amendment. It is only in the proposed amendment in the After-Final amendment that Applicant introduces the term "collapsed". Examiner would also like to note that the proposed amendment would not make the claims overcome Bodicky since the Bodicky sheath is capable of being collapsed, e.g., upon entering the urethra because of external pressure on the sheath caused by the walls of the urethra, and expanded, e.g., upon introduction of fluid in the lumen of the sheath. The Bodicky sheath need not even increase or decrease in diameter to anticipate the proposed claims.